

**AIR FORCE PLAN
FOR IMPLEMENTING THE
ANTHRAX VACCINE IMMUNIZATION PROGRAM (AVIP)
UNDER POST
EMERGENCY USE AUTHORIZATION (EUA) CONDITIONS**

Release Date: 24 Jan 06

Expiration Date: *Until Rescinded by AF/XO*

NOTE TO ALL COMMANDERS: Effective 15 Dec 05, officials from the Food and Drug Administration (FDA) issued a final order finding that Anthrax Vaccine Absorbed (AVA) is safe and effective against all routes of exposure to anthrax spores, including inhalation. Because this regulatory action removed the basis and need for the emergency use authorization (EUA) that DoD has followed since Apr 05, DoD did not seek renewal of the EUA for use of anthrax vaccine to prevent inhalation anthrax. While our senior civilian leaders complete a policy review, DoD will continue voluntary anthrax vaccinations IAW guidelines for the EUA (as outlined in this plan). No personnel other than those designated as previously eligible under the EUA may receive vaccination. This interim approach will continue to include educational briefings, an option to refuse, and reporting requirements.

Chapter 1

INTRODUCTION

1.1. Purpose. This plan directs and provides guidance for the implementation of the Anthrax Vaccine Immunization Program (AVIP) under the conditions of a Food and Drug Administration (FDA) Emergency Use Authorization (EUA). The EUA is no longer required; however, while our senior civilian leaders complete a policy review, DoD will continue voluntary anthrax vaccinations IAW guidelines for the EUA.

1.2. Background.

1.2.1. On 27 Oct 04, the US District Court for the District of Columbia issued an injunction against the ongoing operation of the AVIP. The Court concluded that the FDA was required by its own procedures to solicit public comments before finalizing its conclusion that anthrax vaccine is safe and effective for protection against inhalation anthrax. The decision was not a comment on the safety of the vaccine. DoD remains confident the AVIP complies with all legal requirements and that anthrax vaccine is safe and effective for protecting against inhalational anthrax.

1.2.2. On 10 Dec 04, the Deputy Secretary of Defense determined there is a potential for a military emergency involving an attack on United States military forces with anthrax. On 22 Dec 04, the Assistant Secretary of Defense for Health Affairs requested the FDA issue an EUA regarding anthrax vaccine to prevent inhalation anthrax. On 14 Jan 05, the Secretary of Health and Human Services declared an emergency justifying the emergency use of anthrax vaccine. The FDA issued the EUA on 27 Jan 05. On 6 Apr 05, the US District Court for the District of Columbia modified its injunction against anthrax vaccinations, permitting limited resumption of the AVIP. On 15 Dec 05, the FDA issued a final order finding anthrax vaccine to be safe and effective in preventing anthrax, regardless of route of exposure. This order made the emergency use authorization unnecessary; therefore DoD did not request extension of the EUA. However, as of 24 Jan 06 the legal issues surrounding the US District Court injunction have not been resolved, and DoD has elected to continue a voluntary program while policy issues are reviewed. All conditions that were implemented under the EUA will continue.

1.2.3. The two major conditions of the EUA, which are required in the current AVIP policy are as follows:

1.2.3.1. First, the Services **must** implement an education and information program for potential recipients of the anthrax vaccination that informs personnel:

1.2.3.1.1. The FDA has licensed the use of anthrax vaccine for preventing inhalation anthrax.

1.2.3.1.2. Of the significant known and potential benefits and risks of the use of anthrax vaccine, and the extent to which such benefits and risks are unknown.

1.2.3.1.3. Of the option to accept or refuse administration of the anthrax vaccine.

1.2.3.1.4. Of the consequences, if any, of refusing administration of the product.

1.2.3.1.5. Of the alternatives to anthrax vaccine that are available, and of their benefits and risks.

1.2.3.1.6. That each person has the option to refuse anthrax vaccination without punishment, disciplinary action, separation, or loss of entitlement.

1.2.3.2. Second, the Services **must** ensure health care providers and personnel administering anthrax vaccinations are informed of the same items listed above, and that they have available to them a copy of the anthrax vaccine manufacturer's package insert.

1.2.4. Commanders will maintain positive control over the operation of the AVIP under current conditions. Any deviation from a totally voluntary program violates DoD policy.

1.3. Key Messages. Education of all levels of the command structure is imperative to ensure the success of this program. The key messages for the AVIP are:

- Your health and safety are our #1 concern
- The vaccine is safe and effective, and strongly recommended
- The threat from anthrax is deadly and real
- Vaccination offers a layer of protection in addition to antibiotics and other measures that is needed for certain members of the armed forces
- You may refuse anthrax vaccination under the current policy, and you **will not** be punished

1.4. Personnel Authorized to Receive Vaccination.

1.4.1. Military Personnel. Offer vaccination to military personnel serving in:

1.4.1.1. The US Central Command (USCENTCOM) area of responsibility (AOR) or on the Korean Peninsula for 15 or more consecutive days.

1.4.1.2. Special mission units, units with biowarfare or bioterrorism-related missions, and other specially designated missions, as recommended by the Chairman of the Joint Chiefs of Staff (or designee) and approved by USD(P&R).

1.4.2. DoD Civilian Personnel. After completion of any local bargaining obligations, offer anthrax vaccination to emergency-essential (E-E) and equivalent US national DoD civilian employees serving in USCENTCOM AOR or on the Korean Peninsula for 15 or more consecutive days. Other US national DoD civilian employees serving in these areas for 15 or more consecutive days may also receive the anthrax vaccination. For this purpose, "equivalent" personnel means other personnel whose duties meet all the requirements of 10 U.S.C. § 1580, but who have not been designated as "emergency-essential."

1.4.3. Contractor Personnel. If vaccination and related care are authorized in relevant contracts, offer anthrax vaccination to mission-essential (ME) US national

contracted workers serving in USCENTCOM AOR or on the Korean Peninsula for 15 or more consecutive days. Other DoD-contracted workers who are US nationals serving in USCENTCOM AOR or the Korean Peninsula for 15 or more consecutive days may receive the anthrax vaccination.

1.4.4. **Dependents.** Offer vaccination to adult dependents (age 18-65) of personnel in all categories above that reside in USCENTCOM AOR or on the Korean Peninsula for 15 or more consecutive days.

1.4.5. Offer vaccination within 60 days of departure to all categories of eligible personnel (listed above) preparing for deployment or Permanent Change of Station (PCS) to US CENTCOM or Korea. Dependents, DoD civilians, and contractors must present a copy of the orders and proper identification to receive vaccination.

1.4.6. All personnel, all categories, who had their vaccination series interrupted by the halt in the AVIP, but who are not deploying, are not authorized to resume vaccination at this time.

1.4.7. All personnel, all categories, will cease anthrax vaccinations when exiting USCENTCOM, Korea, or roles described in para 1.4.1.2.

Chapter 2

ROLES AND RESPONSIBILITIES

2.1. HQ USAF.

- 2.1.1. AF/XO is OPR for the AVIP.
- 2.1.2. AF/SG is OCR.
- 2.1.3. Develop AF-level policy.
- 2.1.4. Provide program oversight.
- 2.1.5. Coordinate with other agencies (e.g., Military Vaccine (MILVAX) Agency, OSD, Joint Staff).
- 2.1.6. Review and coordinate requests from MAJCOMs for exceptions to policy.
- 2.1.7. As appropriate coordinate with USCENTCOM or USFK on in-theater implementation of the EUA.

2.2. MAJCOMS.

- 2.2.1. Consult with installations on AVIP issues which require command support.
- 2.2.2. Coordinate requests for exceptions to policy with installations and HQ USAF.

2.3. Installation Commanders.

- 2.3.1. Maintain oversight and ownership of the installation AVIP program.
- 2.3.2. Reactivate the base AVIP implementation team.
- 2.3.3. Develop a base implementation plan consistent with DoD and AF guidance. This document can be used as the foundation for the installation's implementation plan.
- 2.3.4. Direct Medical Commander to designate an Officer-In-Charge (OIC) who will coordinate the administrative functions of the AVIP.
 - 2.3.4.1. Air Reserve Components (ARC) only may select an enlisted Senior Health Technician as the AVIP Medical OIC if unable to fill this role with an officer.
- 2.3.5. Ensure all applicable personnel receive appropriate education as outlined in Chapter 4 of this plan.
- 2.3.6. Ensure that the Medical Group maintains a roster of individuals who have received an AVIP trifold brochure when they report to the immunization clinic (Attachment 1).
- 2.3.7. Ensure compliance with program; grant administrative exemptions as appropriate.
- 2.3.8. Submit requests for exception to policy to MAJCOM DO, XO, or XP (as appropriate) for coordination.

2.4. Installation Deployment Officers (IDO).

- 2.4.1. Administer the Wing's deployment process IAW AFI 10-403.
- 2.4.2. Oversee coordination of all deploying units/individuals, as well as AVIP's effect on the deployment process (eligibility and processing line considerations).

2.5. Public Affairs.

- 2.5.1. Provide support and facilitate proactive community education.
- 2.5.2. Coordinate responses to media inquiries.

2.6. Legal.

- 2.6.1. Educate base personnel as needed on relevant legal issues.
- 2.6.2. Answer queries on legal issues related to the AVIP.

2.7. Medical Commanders.

- 2.7.1. Provide oversight for all administrative (medical) and clinical aspects of AVIP under current conditions.
- 2.7.2. Designate an installation AVIP Medical OIC who will coordinate the administrative functions of the AVIP.
 - 2.7.2.1. Air Reserve Components (ARC) only may select an enlisted Senior Health Technician as the AVIP Medical OIC if unable to fill this role with an officer.
- 2.7.3. Educate all appropriate medical personnel on the clinical and policy aspects of the vaccine.
- 2.7.4. Assign appropriate medical representation to Installation AVIP Team.
- 2.7.5. Ensure a process is in place for access to health care for any personnel or dependent who may have an adverse reaction to the vaccine.
- 2.7.6. Ensure those receiving vaccination have all questions answered prior to administration of the shot.
- 2.7.7. Co-sign OIC Compliance agreement form (Attachment 2).

2.8. Installation AVIP Medical Officer-In-Charge (OIC).

- 2.8.1. Determine number of trifold brochures needed for base education and start-up of AVIP under current program and orders trifold brochures from US Army Medical Materiel Agency (USAMMA).
- 2.8.2. Oversee proper management of roster that documents an individual's receipt of AVIP trifold brochure prior to vaccination (Attachment 1).
- 2.8.3. Oversee distribution of proper AVIP trifold brochures.

2.8.4. Submit Compliance Agreement to MILVAX and sends copy to HQ USAF/XOS-FC after ensuring all checklist items have been completed (Attachments 2 and 3).

2.8.5. Develop and submit monthly report by following report instructions and using report template (Attachment 4).

2.9. Individuals Eligible for Anthrax Vaccination.

2.9.1. Receive education on the threat anthrax poses and information on the anthrax vaccine.

2.9.2. Sign that they received a copy of the AVIP trifold brochure.

2.9.3. Read the AVIP trifold brochure.

Chapter 3

WING IMPLEMENTATION ACTIONS

3.1. Reactivate the installation-level AVIP team.

3.1.1. Per the Air Force AVIP Implementation Plan dated 11 Oct 02, CSAF directed the creation of Wing/installation AVIP implementation teams.

3.1.2. Membership includes representatives from the Wing Leadership, Legal, Medical (that will include the AVIP Medical OIC), Public Affairs, Intelligence, Chaplain, Contracting, Military Personnel Flight, and the Installation Deployment Officer.

3.1.3. The team chairperson is a senior line officer.

3.1.4. The team will review existing policy and guidance and ensure all members are fully educated on the AVIP under current conditions.

3.1.5. The team will provide recommendations and expertise for the local command structure for the re-introduction and maintenance of the AVIP.

3.2. Develop a base anthrax vaccine implementation plan IAW existing policy that provides installation-specific procedures. This document can be used as the foundation for your installation plan. The installation plan must address Education, Medical, and Administrative Issues. Detailed AF guidance on these topics is provided in Chapters 4-6.

Chapter 4

EDUCATION PLAN FOR ANTHRAX VACCINATION

4.1. General. Education is the **KEY** to a successful anthrax vaccination program. Commanders at all levels are responsible to educate their personnel before vaccination. This educational program will inform potential vaccinees:

- That the FDA has licensed the anthrax vaccine for prevention of inhalation anthrax
- Of the known and potential benefits and risks of anthrax vaccination
- That there is no other product approved by FDA to prevent anthrax before exposure
- That individuals have the option to accept or refuse anthrax vaccination

The primary mode of providing this education will take the form of the AVIP trifold brochure –dated 16 Dec 05, or later (hereafter referred to as the “trifold”).

4.2. Key Messages:

- Your health and safety are our #1 concern
- The vaccine is safe and effective, and strongly recommended
- The threat from anthrax is deadly and real
- Vaccination offers a layer of protection in addition to antibiotics and other measures that is needed for certain members of the armed forces
- You may refuse anthrax vaccination, and you will not be punished

4.3. Education for Commanders. Fulfilling the trifold and option-to-refuse specifications of the AVIP are essential command responsibilities. Commanders are responsible for ensuring they are properly and fully educated on the anthrax vaccine **prior to** the first shot. The primary modes of providing this education to commanders will take the form of the AVIP trifold brochure and the “AVIP Briefing for Individuals,” available at <http://www.anthrax.mil/whatsnew/fdaorder.asp>. Commanders will review both of these resources. In addition, Commanders are highly encouraged to use their Installation AVIP team as an education resource.

4.4. Education for Individuals. All eligible individuals must receive education before receiving anthrax vaccine. This applies to individuals beginning or resuming the series. Per the Under Secretary of Defense for Personnel and Readiness (USD(P&R)), all individuals eligible for anthrax vaccination under the current policy will be informed that: "you may refuse anthrax vaccination under the current policy, and you will not be punished. No disciplinary action or adverse personnel action will be taken. You will not be processed for separation, and you will still be deployable. There will be no penalty or loss of entitlement for refusing anthrax vaccination."

4.4.1. The primary mode of providing this education to individuals will take the form of the AVIP trifold brochure –dated 16 Dec 05, or later, which can be downloaded from the AVIP website at: <http://www.anthrax.mil/whatsnew/fdaorder.asp>. Each

individual will be provided a copy of this brochure before **each** anthrax vaccination. No anthrax vaccinations may be given unless a current version of the trifold is distributed.

4.4.2. Vaccine Eligible Military, E-E Civilians and ME Contractors will be directed to the Immunization Clinic. All education requirements outlined in para 4.4.1. apply. These personnel will notify the Immunization Technician of their decision to accept or decline the vaccination so AFCITA can be updated.

4.4.3. All other personnel eligible for vaccination may report to the Immunization Clinic, but on their own accord. All education requirements outlined in para 4.4.1. apply.

4.4.4. If personnel in para 4.4.2. wish to exercise the option to refuse, commanders will respect that individual decision. Leaders will not discipline the individual for that decision. Commanders will ensure the individual is not harassed or coerced to receive vaccination. Personnel who refuse will be informed that they will not be offered anthrax vaccination again unless a change of circumstances occurs such as change of duty location (e.g. arrival in CENTCOM or Korea), that they may change their decision and request vaccination at any time, and that vaccination requires time to develop immunity.

4.4.5. Immunization Technicians will ask three questions of all eligible personnel in para 4.4.2 and 4.4.3 who present to the Immunization Clinic.

4.4.5.1. All personnel will be asked if they have received a copy of the AVIP trifold brochure prior to immunizing them. If they have not, they must be given a copy of the most current version of the brochure. **Personnel must sign a roster indicating that they have received a copy of the brochure before immunization can occur. (Atch 1)**

4.4.5.2. All personnel will be asked by the Immunization Technician if they have any questions prior to immunization. If they express doubts about the value of anthrax vaccination or if they have questions about the vaccine, they will be referred to an appropriate officer to discuss their concerns (e.g., for health care questions, refer to a member of the AVIP medical cadre, for other questions, refer to the appropriate member of the installation AVIP implementation team).

4.4.5.3. All personnel will be asked if they wish to receive vaccination.

4.5. Education for Medical Personnel. Medical personnel are the primary source of information on the disease, the vaccine, and vaccine side effects. For those individuals who have an adverse event associated with the vaccine, they provide the appropriate treatment and referral, if necessary, for diagnosis and treatment of medical conditions.

4.5.1. **Medical commanders will ensure that healthcare professionals and vaccinators involved with the AVIP review and comply with the contents of the AF/XO message and implementation plan, the current version of the trifold, the AVIP briefing slides, available at <http://www.anthrax.mil/whatsnew/fdaorder.asp>, the vaccine's package insert (shipped with each vial), and understand healthcare-access guidance for all active, reserve, civilian and contractor personnel and others affected by AVIP policy, and procedures for reporting Vaccine Adverse**

Events Reporting System (VAERS) and reasons for medical exemption from anthrax vaccination.

4.5.2. Healthcare personnel that complete the above training must sign and date a Healthcare Personnel AVIP Training Roster maintained by the Immunization Clinic NCOIC (Attachment 5). Training will also be documented in appropriate training records.

4.5.3. Healthcare personnel involved with the AVIP under current conditions must re-accomplish and re-document training at each new duty location. The Immunization Clinic NCOIC will ensure all personnel, including all new personnel, complete and document training prior to working in the Immunization Clinic. In this instance, “all personnel” will include all vaccinators (primary and back-up), clinical supervisors of vaccinators, preventive medicine and public health staff, and relevant healthcare providers (e.g., allergy-immunology, ambulatory care, flight medicine, emergency care), and any other provider designated by the Medical Commander.

Chapter 5

MEDICAL ISSUES

5.1. Dosing Schedule.

5.1.1. The dosage schedule for the anthrax vaccine is 0, 2, 4 weeks, followed by doses at 6, 12, and 18 months with an annual booster to sustain immunity. This is the only dosage schedule currently licensed by the FDA. Do not administer the vaccine on a compressed or accelerated schedule. Under **NO** circumstance is the vaccine to be given at shorter intervals than approved by the FDA. Contact the Vaccine Healthcare Center or the Regional Allergist for questions on the vaccine schedule. Vaccinations should be given on or as soon after recommended dates as possible. Whenever a vaccine dose is received after a scheduled date, adjust the subsequent doses accordingly to ensure the proper interval of time between doses. All vaccinations are given subcutaneously and IAW the current scope of practice. The preferred site is the deltoid region.

5.1.2. People resuming anthrax vaccinations under this policy will continue the dosing series where they left off. They will not need to repeat any doses already received in the series or restart the series. This is consistent with guidance from the Centers for Disease Control and Prevention (CDC), its Advisory Committee on Immunization Practices (ACIP), and is not objectionable to the FDA. When a dose cannot be provided on the specific date suggested by the schedule, provide it as soon thereafter as practical.

5.1.3. During this period, the policy of continuing the vaccine dosing series of six shots plus boosters for all personnel who begin it is suspended. Once an individual rotates out of USCENTCOM or off the Korean Peninsula, vaccinations cease, unless the individual moves into a designated special mission or biodefense unit.

5.2. Pregnancy. Anthrax vaccine is generally deferred during pregnancy. Immunization clinics and providers will display a prominent written sign directing women to alert the technician or provider if they think they might be pregnant. All females of childbearing age will be asked about the possibility of pregnancy prior to receiving the vaccine. The following question, recommended by the CDC, should be used on any locally approved questionnaire/overprint: “For women: Are you pregnant or is there a chance you could become pregnant during the next month?” If women have any questions or concerns, they should consult with their healthcare provider before receiving the vaccine.

5.3. Pre-vaccination Screening. Medically screen patients prior to immunizations to ensure there are no contraindications for receiving the vaccine. Follow current CDC and AF guidelines.

5.4. Required Final Sequence for Administration of Anthrax Vaccine.

5.4.1. Ensure the patient has signed the roster acknowledging receipt of the AVIP trifold brochure.

5.4.2. Ensure the patient understands the right to refuse vaccination and states that they want to receive the anthrax vaccine.

5.4.3. Immediately prior to administration of the vaccine (once vaccine and site are prepared) ask the patient: “Do you wish to receive the anthrax vaccine?” If the patient confirms, administer the vaccine.

5.4. Adverse Reactions. Guidelines and procedures for management of adverse reactions have not changed. Health care providers, authorized vaccine dispensers, and vaccine recipients are highly encouraged to report adverse events to the Vaccine Adverse Events Reporting System (VAERS). See initial Air Force AVIP Implementation Plan dated 11 Oct 02, available at:

https://www.xo.hq.af.mil/xos/xosf/xosfc/CCBRNE_resource/biological/anthrax/data/CS_AF_AnthraxVaccineResumptionMemoandPlan.pdf

5.5. Medical Exemptions. Guidance pertaining to medical exemptions has not changed. See initial Air Force AVIP Implementation Plan dated 11 Oct 02, available at:

https://www.xo.hq.af.mil/xos/xosf/xosfc/CCBRNE_resource/biological/anthrax/data/CS_AF_AnthraxVaccineResumptionMemoandPlan.pdf

5.6. Anthrax Vaccine Tracking.

5.6.1 The Public Health Officer will:

5.6.1.1. Obtain numbers of personnel deploying, including deployment location and duration, from appropriate base organizations (IDO, UDM, XP, and others as applicable).

5.6.1.2. Determine which deployers require to be offered the anthrax vaccine.

5.6.1.3. Forward 90-day projected vaccine requirements to Medical Logistics Office.

5.6.1.4. Enter deployers into the Deployment Tracking Module of Preventive Health Assessment and Individual Medical Readiness (PIMR) software. Vaccine eligible deployers will be reflected as “red” in AFCITA until they present to the Immunization Clinic and accept or decline the anthrax vaccine.

5.6.1.5. Send Commanders a unit status report reflecting personnel due or overdue for anthrax vaccination, or those that still need to report to the immunization clinic for education and to accept or decline vaccination.

5.6.2. The Immunization Clinic will record all vaccinations in AFCITA using current AF guidance, place a copy of the DD 2766C into the medical record, and inform the individual verbally and in-writing, when the next dose is due. The AFCITA worksheet printout can be used for the written notification.

5.6.3. Individuals identified as “due” for next dose will turn yellow in AFCITA and will be placed on the Unit Commander’s Individual Medical Readiness Missing Requirements Roster. If the individual does not present to the Immunization Clinic during the “due” grace period, the individual will turn red in AFCITA, which will affect the unit’s Individual Medical Readiness (IMR) rate. All eligible individuals who are due their next dose must present to the Immunization Clinic, receive and sign for an AVIP trifold brochure, and accept or decline vaccination so AFCITA can be updated.

5.6.4. The Immunization Clinic will record exemption code “MD” in AFCITA for those who decline vaccination. Individuals who decline vaccination will not be placed on the Unit Commander’s Missing Requirements Roster. Individuals coded as “MD” (vaccination declined) in AFCITA, will not adversely affect their unit’s IMR rate.

5.7. Medical Logistics/Vaccine Distribution. The US Army Medical Materiel Agency (USAMMA) is responsible for coordinating the distribution of anthrax vaccine within DoD. The Air Force Medical Support Agency (AFMSA/SGSLC) Procurement Services is the AF distribution point of contact for this program. The Air Force POC can be contacted at DSN 343-4170, or Commercial 301-619-4170.

5.7.1. Base level medical logistics personnel can order the anthrax vaccine from USAMMA by using the on-line Air Force Anthrax Vaccine Request Form. Instruction on ordering can be found at <http://www.usamma.army.mil/vaccines/anthrax/antxhome.htm>

5.7.1.1. When USAMMA receives the vaccine order, they will ship AVIP trifolds to the requestor (one for each dose ordered). Trifolds sent with the vaccine are for Immunization Clinic use only.

5.7.1.2. Upon receipt of AVIP trifolds, vaccine requestor contacts USAMMA. USAMMA verifies over the phone that requestor has received the AVIP trifolds, and also verifies requestor will be available to receive vaccine shipment.

5.7.1.3. USAMMA also checks a MILVAX list to ensure the requestor is from a designated AVIP Compliant Immunization Activity before authorizing shipment of vaccine.

5.7.2. Installations can also order trifolds for use in the education program for Commanders, AVIP team members and other key personnel on base. Additional trifolds to be used for base-wide education or commander’s calls can be ordered directly from USAMMA or downloaded from the MILVAX website.

5.7.2.1. Ordering trifolds for program start-up educational purposes: E-mail USAMMADOC@det.amedd.army.mil or otsg.opscenter21opns@hqda-s.army.smil.mil (Attention: MILVAX). Place “Trifold Order” in the subject line. State number of trifolds needed for education purposes and provide shipping address.

5.7.3. Anthrax vaccine is heat and cold sensitive. The vaccine must be kept at the appropriate storage temperature range throughout the entire vaccination process. It should be removed just prior to giving the shot. This vaccine generally should not be "pre-drawn" for administration. The USAMMA web site provides additional guidance on handling, storage, transportation, and administration of anthrax vaccine.

Chapter 6

ADMINISTRATIVE ISSUES

6.1. AVIP Medical Officer-In-Charge (OIC). Per direction of the AVIP Executive Agent (Military Vaccine Agency, MILVAX), an AVIP Medical OIC will be appointed to coordinate administrative requirements of the AVIP. (Air Reserve Components (ARC) only may select an enlisted Senior Health Technician as the AVIP Medical OIC if unable to fill this role with an officer). The OIC is responsible for **monthly reporting** requirements, ensuring distribution of the correct AVIP trifold, becoming familiar with the conditions of the AVIP, and supporting education requirements of the AVIP. The AVIP Medical OIC should be someone in the Immunization Clinic's chain of command. Specific responsibilities of the OIC are:

6.1.1. Read and understand the requirements for anthrax vaccination under current policy.

6.1.2. Complete the compliance agreement at Attachment 2 and provide a signed copy to MILVAX and HQ USAF/XOS-FC.

6.1.3. If no previous compliance agreement with MILVAX, complete the AVIP checklist at Attachment 3 and submit to MILVAX. If previous EUA compliance agreement certified by MILVAX, ensure compliance with requirements in attachment 3.

6.1.4. Ensure memorandum received from MILVAX designating clinic as an AVIP Compliant Immunization Activity before vaccination program begins if not previously providing anthrax vaccine under the EUA.

6.1.5. Report state of compliance directly to the Military Vaccine (MILVAX) Agency **monthly using the template at Attachment 4**. Once the authorization memorandum is received from MILVAX, **monthly reports must commence within the first five days of the next month**, whether or not any vaccinations are given.

6.1.5.1. The report must include the following items:

6.1.5.1.1. Whether or not anyone was required to receive anthrax vaccination against their will, or without being informed of the option to refuse, or otherwise in violation of the option to refuse.

6.1.5.1.2. In any case in which vaccinations were given without an option to refuse, the report shall include a full explanation of the circumstances involved.

6.1.5.2. Submit report not later **the fifth day of the next month**, describing events of the **previous month**. Copies of the report may be provided to elements up the chain of command, as required by HQ USAF elements or the applicable MAJCOM.

6.1.5.3. If a unit or activity fails to report, MILVAX Agency will contact the alternate points of contact listed on the compliance agreement. If necessary, the MILVAX Agency will contact the Air Force Surgeon General's Office. Vaccine

supply requests will not be honored for units that do not consistently report according to these procedures.

6.1.6. Report any violations of the voluntary AVIP policy to the MILVAX Agency and HQ USAF/XOS-FC as soon as recognized, without waiting for the next report cycle. Use the template and contact information in Attachment 4 for this out-of-cycle reporting.

6.2. Documentation.

6.2.1. Documentation of Education.

6.2.1.1. The installation commander will ensure a process is established that ensures a dated roster (sample template is at Attachment 1) is kept for eligible personnel who present for vaccination that indicates they have received an AVIP trifold brochure--dated 16 Dec 05 or later. This roster will be captioned "By signing, I certify that I have received an Anthrax Vaccine Immunization Program Trifold Brochure (dated 16 Dec 05 or later) and that this was done prior to vaccination.". These rosters will be maintained by the immunization clinic and retained for a minimum of one year. Do not collect signatures on trifold.

Personnel do not sign that they accept or decline anthrax vaccination under current conditions--only that they received a trifold.

6.2.1.2. All personnel, all categories, must sign the roster (Attachment 1) acknowledging receipt of the AVIP trifold prior to vaccination.

6.2.2. Documentation of Vaccinations and Declinations. Vaccinations and declinations will be immediately entered into AFCITA. AFCITA will track when individuals are due for subsequent doses and will indicate their status as green (current), yellow (due), or red (overdue). Declination of anthrax vaccination will be entered into AFCITA by selecting the "MD" exemption code, which means declined. This action will deactivate AFCITA next dose due notification.

6.3. E-E Civilians.

6.3.1. Commanders must identify US-national E-E civilian employees eligible for vaccination and direct them to a military medical unit for education, screening, and vaccination as appropriate. Commanders will provide a list of E-E civilians eligible for vaccination to the MTF/immunization clinic. E-E civilians must present proof they are an E-E employee (e.g., identification card) and immunization record, if available, to medical personnel.

6.3.2. For E-E civilians that are non-bargaining unit members, vaccinations will begin immediately.

6.3.3. For E-E civilians that are bargaining unit members who have already deployed or currently reside in USCENTCOM or on the Korean Peninsula, vaccinations will begin immediately; post-negotiations will be accomplished as deemed necessary.

6.3.4. For E-E civilians that are bargaining unit members who are scheduled to, but have yet to deploy to USCENTCOM or the Korean Peninsula, limited local bargaining obligations (e.g., education) must be met prior to receiving the vaccinations. Upon completion, the servicing civilian personnel flight will inform the

military medical community that bargaining obligations have been completed and commanders will provide a list of E-E civilians eligible for vaccination to the MTF/immunization clinic.

6.4. ME Contractors.

6.4.1. Vaccination of US-national ME contractor personnel will be a requirement of the applicable contract.

6.4.2. If not already done, commanders must, IAW existing SAF/AQC guidance, identify their mission essential services and inform the cognizant contracting officers. Contracting officers will modify contracts that do not already cover the designated mission essential services. Contracting officers should take appropriate actions to modify contracts to address: identification of the mission essential services; the contractor's responsibility to identify their employees who will perform the mission essential services during a crisis; funding and liability; and authorization for vaccination and related medical care.

6.4.3. Once mission essential services are contractually covered, contracting officers will direct contractors to identify their mission essential vaccine eligible employees. Contracting officers will provide a list of these employees to commanders and the MTF/immunization clinic. Commanders will then direct ME contractor personnel to a military medical unit for education, screening, and vaccination as appropriate.

6.5. Others Eligible for Vaccination.

6.5.1. Voluntary vaccinations are authorized for the following individuals who are deployed to, or residing in, Korea and the USCENTCOM AOR (unless medically exempt): all non-E-E civilian personnel (to include non-appropriated fund employees), adult family members of US national DoD civilian personnel, all US-national DoD contractor personnel not designated as providing mission essential services if contract authorizes vaccination and related medical care, and adult dependents of all US-national contractor personnel (ME or non-ME). Individuals volunteering for vaccinations must present proof (e.g., identification card) they fall into one of the above categories and an immunization record, if available, to medical personnel.

6.5.2. Voluntary vaccinations under the Department of State (DoS) vaccination program continue to be authorized for Air Force personnel (military and their adult dependents, E-E and non-E-E civilians and their adult dependents, and ME and non-ME contractor personnel) serving at DoS missions.

6.5.3. While the current policy is in effect, individuals voluntarily receiving the anthrax vaccines **will not** sign the previously required form "Anthrax Vaccine Immunization Program (AVIP) Information Statement and Acknowledgement" prior to vaccination.

6.5.4. Non-ME contractor personnel volunteering for anthrax vaccinations may not be vaccinated until their employer's contract authorizes the vaccines. Affected contracts will address procedures for the contractor to submit a listing of personnel volunteering to be vaccinated to the contracting officer and for the contracting officer to annotate the listing with an approval statement. Employers will give each

volunteer a copy of the listing that must be presented along with an appropriate form of personal identification to the immunization clinic in order to be eligible for the vaccines.

6.6. Exceptions to Policy (ETPs).

6.6.1. During this period, groups previously granted ETPs **will not** be eligible for vaccination unless those requests are re-coordinated with HQ USAF/XOS-FC.

6.6.2. Requesting ETPs.

6.6.2.1. Exceptions to policy (ETPs) for the AVIP require approval by the USD(P&R). There are two ways to request an ETP. The first is to submit an official request for an ETP from the Wing level through the MAJCOM to HQ USAF/XOS for action. The second is to submit the request for an ETP through the appropriate COCOM, who will in turn submit to the Director, Joint Staff. Generally, the requests should only be sent up to the COCOM if the ETP is for more than one Service. If the ETP will affect only Air Force personnel, the request should be sent up through Air Force channels.

6.6.2.2. To make the strongest case possible to the USD(P&R) for an ETP, requests from the Wing should have a cover memo from the Wing/CC that contains the request and supporting rationale. The memo should have as an attachment a Point Paper that provides key figures on the situation that warrants the request. This includes information on the number of personnel to be vaccinated, the mission/role of the personnel, and the specific reason current policy does not permit vaccination. HQ USAF/XOS-FC can assist the Wing and MAJCOMs in drafting their requests and provide general advice on the likelihood of approval.

6.6.2.3. The Wing/CC should submit the request to their MAJCOM Operations or Plans community (as appropriate) for endorsement and forwarding to HQ USAF/XOS. HQ USAF/XOS will staff the request through appropriate HAF offices and up to the Director, Joint Staff, which (if they concur with the request), will staff it up to the USD(P&R) for approval.

6.7. Waivers and Exemptions.

6.7.1. General. IAW current policy, all individuals eligible for anthrax vaccination may refuse anthrax vaccination. No disciplinary action or adverse personnel action will be taken against them, they will not be processed for separation, and they will still be deployable. There is no penalty or loss of entitlement for refusing anthrax vaccination. Despite the fact that the vaccination is voluntary, there are still several administrative exemptions that remain applicable:

6.7.2. With the exception of the right to refuse the vaccination, guidance pertaining to other administrative and medical exemptions, as well as religious waivers, has not changed. See initial Air Force AVIP Implementation Plan dated 11 Oct 02, available at:

https://www.xo.hq.af.mil/xos/xosf/xosfc/CCBRNE_resource/biological/anthrax/data/CSAF_AnthraxVaccineResumptionMemoandPlan.pdf

6.8. Healthcare Access Guidelines. Guidelines for access to healthcare have not changed from the initial Air Force AVIP Implementation Plan dated 11 Oct 02, available at:

https://www.xo.hq.af.mil/xos/xosf/xosfc/CCBRNE_resource/biological anthrax/data/CS AF AnthraxVaccineResumptionMemoandPlan.pdf

Attachment 1 -- Sample Trifold Roster

Education Roster, Anthrax Vaccine Immunization Program (AVIP)						
Installation/Clinic:						I certify that I have received an AVIP Trifold Brochure (dated 16 Dec 05 or later) and that this was done prior to my being offered the vaccine. (Please check) <input checked="" type="checkbox"/>
Date	Name & Rank			Signature	Unit	
	(Please Type or Print Legibly)					
	Rank	Last	First			
						<input type="checkbox"/> Yes
						<input type="checkbox"/> Yes
						<input type="checkbox"/> Yes
						<input type="checkbox"/> Yes
						<input type="checkbox"/> Yes
						<input type="checkbox"/> Yes
						<input type="checkbox"/> Yes
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						<input type="checkbox"/> Yes
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						<input type="checkbox"/> Yes
						<input type="checkbox"/> Yes
						<input type="checkbox"/> Yes

PRIVACY ACT STATEMENT Data requested is being collected under the authority of the Privacy Act of 1974, 5 U.S.C., Section 552a; 5 U.S.C. 301, Departmental Regulations; 10 U.S.C. 3013; and E.O. 9397 (SSN). Information will not be released outside the Department of Defense unless authorized in 5 U.S.C., Section 552a.

Also available for download as an Excel Spreadsheet at:

https://www.xo.hq.af.mil/xos/xosf/xosfc/CCBRNE_resource/biological/anthrax/index.asp

Attachment 2

AVIP MEDICAL OFFICER-IN-CHARGE (OIC) COMPLIANCE AGREEMENT

AVIP Medical Officer-in-Charge (OIC): read, sign, and return to address below.

I have read and understand the HQ USAF/XO message dated 20 Jan 06 at this url: https://www.xo.hq.af.mil/xos/xosf/xosfc/CCBRNE_resource/biological/anthrax/index.asp describing requirements for anthrax immunization. I recognize the 22 Dec 05 policy against involuntary anthrax immunization.

Each of the items on the checklist (AF Implementation Plan, Attachment 3) has been fulfilled for our unit or activity. I have included a copy of the completed checklist with this request. I understand the monthly reporting requirements (AF Implementation Plan, Attachment 4). If the Military Vaccine (MILVAX) Agency does not receive a report on time, they may contact the people named below to obtain another copy.

For medical units: My staff has informed or reminded every healthcare worker with responsibilities for administering anthrax immunizations (including immunization backup technicians) of the importance of confirming desire to receive anthrax vaccine before the actual injection. The final sequence involves ensuring the patient received an educational brochure and understands the right to refuse. Just before injection (once site and vaccine are prepared) ask the patient 'Do you want to receive the anthrax vaccine?' If the patient confirms, administer it. These steps are intended to prevent medication errors.

Our unit or activity is ready to comply with the DoD policies for anthrax vaccination. I accept responsibility for AVIP trifold distribution, education and monthly reporting.

If I am assigned other duties and am no longer the AVIP Medical OIC, I will notify the MILVAX Agency before departure. I will instruct my replacement to complete his or her own Compliance Agreement and forward it to the MILVAX Agency.

AVIP OIC (printed name, title)

(signature)

(date)

DSN telephone:

E-mail address:

Medical Commander (printed name, title)

(signature)

(date)

This agreement corresponds to immunization team(s) for the following unit, activity, or vaccination clinic: (Unit or activity name, address and zip code)

The medical activity storing anthrax vaccine and administering the anthrax immunizations (Medical unit or activity name, address and zip code)

Alternate points of contact (Name, DSN telephone number, email)

- 1.
- 2.
- 3.

Send To: Director, Military Vaccine Agency, fax: 703-681-4692, DSN 761-4692. NIPR: vaccines@otsg.amedd.army.mil. SIPR: otsg.opscenter21opns@hqda-S.army.Smil.mil (Attention: MILVAX). Voice: 703-681-5101, DSN 761-5101. Director will return an acknowledgment letter, authorizing receipt of anthrax vaccine shipments.

Courtesy Copy To: HQ USAF/XOS-FC, fax: 703-614-7221, DSN 224-7221. E-mail: NIPR: AFXOSFC.Workflow@pentagon.af.mil. SIPR: AFXOSFC.Workflow@af.pentagon.smil.mil. Please use subject line "AVIP OIC". Voice: 703-692-5806, DSN 222-5806.

Attachment 3

AVIP IMPLEMENTATION CHECKLIST

Unit: _____ Location: _____

AVIP Medical OIC: _____ Date Checklist Completed: _____

Ensure these items have been completed before giving anthrax vaccinations:

- ☐ 1. Collect all AVIP trifold brochures from 15 Dec 2005 or earlier and discard them. Do not retain them for future use. Be sure to remove obsolete trifold brochures from pamphlet racks in waiting rooms, on bulletin boards, intranets, etc.
- ☐ 2. Obtain sufficient AVIP trifold brochures dated 16 Dec 05 or later, enough to give a personal copy to each person to be vaccinated, one for each dose. Each anthrax vaccine shipment will include AVIP trifold brochures equal to the number of doses ordered. Additional color copies of these revised trifold brochures are available by emailing usammadoc@det.amedd.army.mil or at www.anthrax.mil/FDAOrder.
- ☐ 3. Obtain AVIP briefing slides. Available from www.anthrax.mil/FDAOrder. If you need these slides shipped to you in hard copy or on a CD-ROM, call 877-GET-VACC or send an email request to vaccines@otsg.amedd.army.mil, SIPRNET otsg.opscenter21opns@hqda-S.army.mil (Attention: MILVAX).
- ☐ 4. Air Force AVIP Post EUA Conditions Implementation Plan, Attachment 1, provides a prototype AVIP education roster. Use AVIP education rosters only to confirm that each person to be offered anthrax vaccination received an AVIP trifold brochure before each dose. This roster will be captioned "I received an AVIP trifold for anthrax vaccine" or words to that effect. Rosters will include printed or typed name and date trifold received. Retain these rosters with unit records for one year. **Do not** collect signatures accepting/declining vaccination on trifold brochures or any other document. Personnel **do not** sign that they accept or decline anthrax vaccination, only that they received the AVIP trifold brochure.
- ☐ 5. Coordinate with supporting medical activity or ensure organic medical support has required AVIP training for vaccinators and healthcare providers. Assure all vaccinators (primary and back-up), clinical supervisors of vaccinators, preventive medicine and public health staff, and relevant healthcare providers (e.g., allergy-immunology, ambulatory care, flight medicine, emergency care) are familiar with the clinical science for anthrax vaccine and DoD requirements. Use training course available at www.anthrax.mil/education/clinician/clinicians.asp. Annotate training records accordingly. Vaccinators acknowledge the content in the following materials:
 - a. HQ USAF/XO message, "Extension of Authorization for Anthrax Vaccinations", AF Plan for Implementing the AVIP under Post EUA conditions, 24 Jan 06.
 - b. AVIP healthcare provider briefing slides at www.anthrax.mil/education/clinician/clinicians.asp

- c. BioThrax package insert: available with every vaccine vial or at www.bioport.com/AnthraxVaccine/Insert/AVAIInsert.asp.
 - d. AVIP trifold brochure dated 16 Dec 05 or later.
 - e. Healthcare-access guidance for all active, reserve, civilian and contractor personnel, and others affected by current AVIP policy.
 - f. Reporting procedures for Vaccine Adverse Events Reporting System (VAERS) at www.vaers.hhs.gov.
 - g. Reasons for medical exemption from anthrax vaccination (e.g., serious allergic reactions to anthrax vaccination, moderate or severe illness, pregnancy, latex sensitivity, immune-suppressive conditions, Guillian-Barré syndrome, previous anthrax infection). The most effective way to identify early pregnancy is to ask discreetly for date of last menstrual period and whether the last menses was normal and on time. Offer pregnancy testing before any immunization.
- [] 6. Assure health care personnel above sign a training roster maintained by the Immunization Clinic NCOIC that documents name and date training completed.
- [] 7. Understand criteria for eligibility for anthrax vaccination (Under Secretary of Defense (P&R) memo, 29 Apr 05; HQ USAF Post EUA implementation plan, available at https://www.xo.hq.af.mil/xos/xosf/xosfc/CCBRNE_resource/biological/anthrax/index.asp).
- [] 8. Inform or remind every healthcare worker with responsibilities for administering anthrax vaccinations (including immunization back-up technicians) of the importance of confirming desire to receive anthrax vaccine before the actual injection. The final sequence involves ensuring the patient has signed the roster to acknowledge receiving the AVIP trifold brochure, and understands the right to refuse. Immediately prior to administration of the anthrax vaccine (once site and vaccine are prepared) ask the patient “Do you wish to receive the anthrax vaccine today?” If the patient confirms, administer it. These steps are intended to prevent medication errors.
- [] 9. Assure OIC or commander understands the need for officer(s) not directly involved in the AVIP to perform spot checks of anthrax immunizations operations to assure the option to refuse can be freely exercised.
- [] 10. Understand the option to refuse, including both (a) the reasons why the military and civilian leadership of the Armed Forces strongly recommend vaccination, as well as (b) the requirement that no one can be ordered or forced to be vaccinated under the current DoD policy.
- [] 11. Assure clinic has sufficient trained personnel with passwords to enter vaccination data into AFCITA at the time of vaccination or has a plan to train them expeditiously and can assuredly record immunizations on SF Form 601, DD Form 2766, Deployable Medical Record, PHS Form 731, or similar form.

- [] 12. Assure clinic supervisor or commander understands **monthly reporting requirements** regarding option to refuse. These reports go directly to the Military Vaccine Agency, at the direction of the Deputy Secretary of Defense.
- [] 13. Assure clinic and medical logistics personnel have been trained in cold-chain management procedures, including prompt refrigeration of vaccines upon receipt. [Or freezing, in the case of *YF-Vax*, *Varivax*, and *FluMist*]. Alarm systems are used to protect large inventories.

Reassess items on this checklist periodically.

Attachment 4

AVIP MONTHLY REPORT TEMPLATE

MEMORANDUM FOR Director, Military Vaccine (MILVAX) Agency

Fax: 703-681-4692, DSN 761-4692. Voice 877-GET-VACC. DSN 761-5101

NIPR: vaccines@otsg.amedd.army.mil

SIPR: otsg.opscenter21opns@hqda-S.army.Smil.mil (Attention: MILVAX)

SUBJECT: Report of Compliance with Conditions for Anthrax Vaccine Immunization Program (AVIP)

1. Report for the monthly interval from _____ through _____:

[If the following sentence is true, submit it as your report. If the following sentence is not true, change the text to explain what occurred to make the proposed text untrue. Be sure to specify the number of people vaccinated without an option to refuse and be prepared to provide a list of their names.]

No one received anthrax immunization against his or her will, or without being informed of the option to refuse, or otherwise in violation of the option to refuse, at this unit.

2. Remedy. [If applicable, describe here steps taken to prevent noncompliance with DoD policy from happening again. If not applicable, state “not applicable.”]

3. I certify the accuracy of this report to the best of my knowledge.

Name

Title

Date

If faxed, sign on line above. If emailed, send as scanned PDF document or from approving authority's or alternate official's email account.

Contact email: _____

Contact telephone #: _____

Unit Address and Zip Code:

Attachment 5 -- Sample Healthcare Personnel Training Roster

[illegible]

Also available for download as an Excel Spreadsheet at:

https://www.xo.hq.af.mil/xos/xosf/xosfc/CCBRNE_resource/biological/anthrax/index.asp